PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Zhang**
Application No.:	**09/672,330**
Filed:	**September 28, 2000**
For:	**Process for Forming a Medical Device Balloon**
Examiner:	**Monica Fontaine**
Group Art Unit:	**1732**

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2-9176-US01

RESPONSE TO FINAL REJECTION

Reconsideration of the Final Rejection mailed October 1, 2003 is requested. The Examiner has clearly erred in maintaining the rejection of claims 1-4 and 6-12 as anticipated by Jackowski et al., US 5,017,325 ("Jackowski"), and in rejecting claim 5 as obvious from Jackowski, taken with Hamlin, US 5,270,086.

The factual determination of anticipation requires the disclosure in a single reference of every element of the claimed invention. *Ex parte Levy*, 17 USPQ2d 1461 (BdPatApp&Int 1990), *citing, In re Spada*, 15 USPQ2d 1655 (Fed. Cir. 1990); *In re Bond*, 15 USPQ2d, 1566 (Fed. Cir. 1990); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 7 USPQ2d 1315 (Fed. Cir. 1988); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 7 USPQ2d 1057 (Fed. Cir. 1988); *Alco Standard Corp. v. TVA*, 808 F.2d 1490, 1 USPQ2d 1337 (Fed. Cir. 1986); *In re Marshall*, 578 F.2d 301, 198 USPQ 344 (CCPA 1978); *In re Arkley*, 455 F.2d 586, 172 USPQ 524 (CCPA 1972).

To support an obviousness rejection, the cited prior art must specifically suggest *the combination as claimed*, and it must be applied in the context of their significance to a technician at the time the invention was made, *without knowledge of the applicant's solution*. It is impermissible, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template, picking and choosing among isolated disclosures in the various documents to supply elements to fill the gaps. The cited documents themselves must

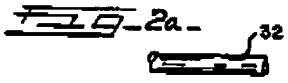
provide some teaching whereby the applicant's combination would have been obvious, again at the time the invention was made. U.S. patent law is replete with cases that illustrate this principle. *See e.g. In re Fine*, 37 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988); *In re Gorman*, 18 USPQ2d 1885, 1888 (Fed Cir. 1991); *In re Oetiker*, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992); and *In re Fritch*, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992).

The Examiner has not made the required showings for either of the outstanding the anticipation or the obviousness rejections.

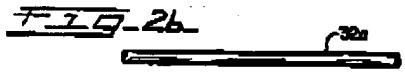
In particular, claim 1 recites axially stretching an extruded tubing segment made of a polymer material, while pressurizing the tubing at an internal pressure above ambient pressure, the pressurization occurring at a temperature which results in an expansion of the internal diameter of the tubing. The Examiner has clearly erred in stating that this feature is found in Jackowski. Jackowski clearly teaches axial stretching steps which are separate from the radial expansion steps. Pressurization while axially stretching does not occur in the Jackowski process.

Jackowski discusses the sequence of steps for forming balloons twice in the specification, the first a general description which is not apparatus dependent, and second a description of the implementation of the process in the specific apparatus of the invention. Neither of these descriptions teaches or suggests that the tubing is pressurized during an axial stretching step.

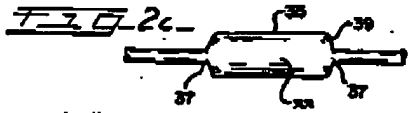
The following table walks step-wise through the first of these two process descriptions.

Step	Patent text	Comment
1. Extrude tube	In an exemplary application, tubing length 32 is extruded so that it exhibits a diameter that is roughly one-quarter of the diameter intended for the balloon. The extruded tubing length 32 also has a nominal wall thickness that is on the order of six to twelve or so times the desired wall thickness of the balloon 33, 34. col. 5, lines 25-30.	This step sets the reference diameter for the extruded tube. This is the tube shown in Fig. 2a.
		
2. Stretch	***FIG. 2b illustrates tubing length 32a, which is***	This is relevant to

axially at room temperature (initial stretch)	***tubing length 32, after it has been axially oriented or elongated to approximately three times its original length. This elongation or drawing procedure is carried out at approximately room temperature,*** and same proceeds typically until is has been stretched to the point that it exhibits a noticeable resistance to further stretching. Typically, the pull force is greater than the yield point of the particular tubing length 32, but less than the ultimate tensile strength, lengthwise, of the selected material. ***Generally speaking, this axial elongation procedure is carried out until the wall thickness of the tubing length 32a is roughly one-half of the wall thickness of the tubing length 32 and/or until the diameter of the tubing length 32a is roughly one-half to forty percent of the outer diameter of the tubing length 32.*** The actual stretched length can typically be about two times to about four times or more of the original tubing length 32. Actual stretching of the tubing 32 can be performed by simply axially stretching length 32 or by pulling or drawing length 32 through a sizing die. col. 5, lines 31-51	applicant's claim 1. This step in Jackowski ***reduces*** the tube thickness and outer diameter of the extruded tube. Pressurization at this point in time is neither taught nor suggested. It cannot reasonably be argued that the inner diameter will increase during this step.



3. Radially expand the tube under pressure. without a mold- form ("free-blowing" step)	***FIG. 2c illustrates a step that is carried out after the longitudinal orientation procedure of FIG. 2b has been completed.*** This is a biaxial orientation step by which a portion of the tubing length 32a expands primarily radially and thereby delineates the balloon portion 35 from the leg portions 37. ***This biaxial orientation is carried out by pressure exerted on the inside wall of the tubing length 32a by a pressurized fluid.*** Typically, the balloon portion 35 will have an outer diameter that is on the order of roughly six times the outer diameter of the tubing length 32a. The pressurized fluid may include gases such as compound air, nitrogen or argon. Liquids such as water or alcohol could also be used if they do not pose a problem of leaving residual fluid in the balloon. col. 5, lines 52-64	This is the ***first*** time the tubing sees elevated pressure and it doesn't occur until the parison has already been stretched. This is clearly taught as a separate step from the axial stretching step. Therefore the product of this step is not relevant to claim 1.



4(a). Skip to heat set (step 6), or	A satisfactory balloon can be prepared by proceeding with the method through and including the step illustrated in FIG. 2c, followed by dimensional stabilization, heat setting or thermoforming, the balloon to near its biaxially oriented profile and size by maintaining its elevated temperature until the selected material is thermally set. Tailorability that is achieved according to this invention is a function of the particular heat setting conditions. The setting temperature can vary with the type of material used, the wall thickness, and the treatment time. A typical setting temperature is between about 100° C and about 160° C for a nylon material, and a typical time is from about 1 minute to about 4 minutes. Col. 6, lines 44-57	If heat set at this point, the balloon forming process is terminated upon completion.
4(b). Stretch axially at room temperature (second stretch).	Regarding FIG. 2d, the balloon 33 of FIG. 2c, which is not thermally set, is again longitudinally oriented by applying an axially directed force that is typically greater than the yield point but less than the ultimate tensile strength of the balloon 33. ***This may be carried out at approximately room temperature.*** If desired, the magnitude of this axial force can be substantially the same as the magnitude of the axial force applied in the procedure illustrated in FIG. 2b. Col. 7, lines 3-11	Nothing is said about pressurization in this step.
5. Radially expand a second time in a mold form. ("mold- blowing" step)	***Further biaxial orientation is then conducted by, for example, introducing a pressurized fluid into the balloon lumen*** in order to prepare the balloon 34 shown in FIG. 2e. It is often desirable to conduit this procedure within a mold cavity in order to thereby effect a careful shaping of the balloon portion 36, the leg portions 38, and the tapered connection surfaces therebetween, generally as desired. Col. 7, lines 11-18	Again, pressurization occurs *after* axial stretching.
6. Heat set	Whether the procedure is utilized that forms the balloon 33 or if the procedure is continued such that the balloon 34 is formed, the thus formed balloon 33, 34 is preferably then subjected to a heat setting step at which the still pressurized balloon 33, 34 is heated to	

set the expanded dimensions thereof.
Col. 7, lines 25-30

The Examiner relies, in part, on Figure 2c of Jackowski. This reliance is clearly misplaced since that figure shows a product of step 3, above, i.e. after ***both*** the axial stretching and the free-blowing steps have been performed. It is not representative of the product of the axial stretching step. Jackowski's Figures 2a, showing the parison as extruded, and 2b, showing the axially stretched parison, are relevant to the applicant's claim. Based on the amount of reduction in OD between those two figures, it appears that the ID in Fig 2b must also have been reduced. The ID certainly is not enlarged as recited in applicant's claim 1.

The Examiner also cites three sentences from column 10 for an alleged teaching that "the chamber [*sic*] in which the parison is stretched is pressurized, therefore achieving stretching while pressurizing." Initially, it appears that the Examiner may have completely misunderstood the processes involved. In ***both*** the applicant's claim 1 and in the Jackowski patent, it is the ***parison*** in the chamber, not the chamber itself, which is pressurized.

Further, if the Examiner's statement is corrected to refer to pressurization of the parison, rather than the chamber, the cited sentences in column 10 do not teach "stretching while pressurizing." Rather, these sentences occur within a second discussion of the Jackowski process, which begins at col. 8, line 32, and which describes the same sequences, this time as implemented with Jackowski's balloon blowing apparatus.

Two of the three sentences from column 10, which the Examiner relies upon for the rejection, occur in the following paragraph:

> Generally speaking, it is usually advantageous that the temperature in the molding chamber 56 be higher than that applied in the free-blow chamber 55, while at the same time imparting a pressure to the inside walls of the parison within the molding chamber 56 that is equal to or lower than the pressure applied in the free-blow chamber 55. For example, when a nylon is the material, the temperature in the free-blow chamber 55 can be slightly above ambient, preferably in a range of between about 30° C and 60° C, while the temperature in the molding chamber 56 can be at the high end of this range or even well above, as needed. *Exemplary pressures would include on the*

> *order of ten atmospheres in the molding chamber 56 and twice that pressure or greater in the free-blow biaxial orientation chamber 55. The exact pressure is determined by the material and by the wall thickness and hoop stress of the balloon to be molded.*
>
> Col. 9, line 67- col. 10, line 16

The italicized sentences are those cited by the Examiner. Nothing in these sentences teaches, suggests, or even hints, that we have switched to a different process sequence than what had already described. There is no sequence information in this paragraph at all. This paragraph clearly is describing the temperatures and pressures employed at those times when pressure and heat are applied according to the sequences already described. That is, only during the separate free-blowing, mold-blowing and heat set steps.

The intermittent character of these heat and pressure parameters is made even clearer by the next paragraph:

> ***With heat thus imparted*** to the modified biaxially orientated balloon 34 with the molding chamber 56, the balloon 34 is thereby thermoformed, with heat setting in this regard involving raising the temperature of the thermoplastic while it is under inflated stress. ***Thereafter, the heated fluid within the fluid jacket 65 is exchanged for cooling fluid*** in order to substantially maintain the size and shape of the balloon 34 formed within the molding chamber 56. ***After the pressure has been relieved, the balloon is removed*** from the apparatus. Subsequently, the thus modified parison is severed generally along lines A and B as illustrated in FIG. 2e in order to thereby form the balloon 26 for inclusion within a medical device such as catheter 21.
>
> Col. 10, lines 17-30.

Since Jackowski is clearly contemplating only intermittent heating and pressurization, it cannot logically be inferred that either of the initial or the second axial stretching steps occur under pressure merely because they occur as the parison is advanced into the respective free-blowing and mold-blowing chambers where pressurization will occur. To the contrary, as we have shown above, pressurization is taught ***only after*** axial stretching has been performed.

A third sentence from column 10 is also cited in the Final Action for the assertion that Jackowski achieves "stretching while pressurizing." That sentence follows:

> After initial stretching and formation of a balloon 33 within the free-blow chamber 55, the apparatus is utilized so that the portion of the parison within the molding chamber 56 is radially expanded before that within the free-flow chamber 55, which generally occurs as follows.
>
> Col. 10. lines 35-39

The assertion that Jackowski "achieves stretching while pressurizing" is also not supported by this sentence. As we have seen Jackowski teaches performing an initial axial stretching step, followed by a free-blowing radial expansion step. This sentence merely refers to a point in time after they have ***both*** been completed. There is nothing in this sentence, or anywhere else in the Jackowski patent, which can reasonably be asserted to teach, or suggest, pressurizing during axial stretching merely because the next step, free-blowing, employs pressurization.

Conclusion

The Final Action misstates the invention and misreads the Jackowski patent. Jackowski teaches separate axial stretching and radial expansion steps. The parison is not pressurized during Jackowski's axial stretching step. Consequently Jackowski does not anticipate claims 1-4 and 6-12 and does not render claim 5 obvious when taken with Hamlin. The rejections should be withdrawn and the application passed to issue.

Respectfully submitted,
VIDAS, ARRETT & STEINKRAUS

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By: _____
Walter I. Steinkraus
Registration No.: 29592

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9185
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

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